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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,092	11/19/2001	Jeffrey L. Garwin	13222.00014	9289

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EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,092	GARWIN, JEFFREY L.	
	Examiner	Art Unit	
	RANDALL WINSTON	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-30, drawn to a method to determine if a sample of cells contains dysplastic or carcinomic cells, classified in class 435, subclass 7.23, for example.
 - II. Claim 31, drawn to a method of diagnosing a patient for early-stage cancer or a precancerous condition, classified in class 435, subclass 4, for example.
 - III. Claims 32-33, drawn to a method of prognosing a patient's response to a cancer therapy the method comprising prior to the therapy, performing the method of claim on a sample of cells from the patient's tissue or organ being treated for the cancer at intervals then determining etc., classified in class 435, subclass 40.5, for example.
 - IV. Claims 34 drawn to a method of prognosing a patient's response to a cancer therapy the method comprising prior to the therapy, performing the method of claim on a unfix sample of cells from the patient's tissue or organ being treated for the cancer then separating, treating, and observing etc., classified in class 435, subclass 7.23, for example.

- V. Claims 35-36, drawn to a method of detecting dysplastic or carcinomic cells in selected target tissue of a patient, classified in class 435, subclass 4, for example.
- VI. Claims 37-40, drawn to a method of making a TCPP solution, classified in class 435, subclass 325, for example.
- VII. Claims 41-45, drawn to a composition comprising TCPP, classified in class 435, subclass 325, for example.
- VIII. Claims 46-48, drawn to a kit comprising TCPP in a container, classified in class 600, subclass 300, for example.

- 2. The inventive groups above are directed to different inventions which are not connected in design, operation, and/or effect. These claimed methods such as Inventions I-VI methods are distinguishable, each from the other, because they are six unrelated methods. The six method's preamble and/or objectives are either a method to determine if a sample of cells contains dysplastic or carcinomic cells or a method of diagnosing a patient for early-stage cancer or a precancerous condition or a method of prognosing a patient's response to a cancer therapy the method comprising prior to the therapy, performing the method of claim on a sample of cells from the patient's tissue or organ being treated for the cancer at

intervals then determining etc. or a method of prognosing a patient's response to a cancer therapy the method comprising prior to the therapy, performing the method of claim on a unfix sample of cells from the patient's tissue or organ being treated for the cancer then separating, treating, and observing etc or a method of detecting dysplastic or carcinomic cells in a selected target tissue of a patient or to a method of making a TCPP solution. Therefore, these six unrelated methods utilize different steps and/or approaches to achieve its preamble objective.

Moreover, the claimed composition (i.e. Invention VII) and/or the claimed kit (i.e. Invention VIII) are distinguishable, each from the other, because they are unrelated products. The two unrelated products are either a composition comprising TCPP or a kit comprising TCPP in a container. Therefore, they are unrelated products.

Furthermore, the composition and/or kit and/or methods are not disclosed as capable of use together because they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods and/or use of a kit and/or use of a composition at the same time to practice just one method alone and/or one kit and/or one composition alone.


3. The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as separate subject for inventive effect and require independent searches (as indicated by the different

classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all the above inventions in one application.

Applicant is advised that the reply to this requirement to be completed must include an election of the invention to be examined even though the requirements be traversed (37 CFR 1.143).

An inquiry concerning this communication should be directed to Randall Winston at telephone number (703) 305-0404. The examiner can normally be reached during the hours of 08:30 to 17:00 Eastern.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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